

**ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT
WITH A SPACER AND METHOD**

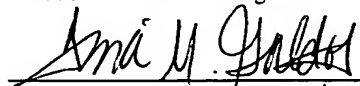
INVENTOR:

STEVE MITCHELL

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**ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT
WITH A SPACER AND METHOD**

INVENTOR:

STEVE MITCHELL

CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No 60/422,022, which was filed October 29, 2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH A SPACER AND METHOD," which is incorporated herein by reference.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] This application is related to U. S. Provisional Application No. 60/422,039, filed October 29, 2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND METHOD" (Attorney Docket No. KLYCD-05007US0), U.S. Patent Application No. 10/____, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND METHOD" (Attorney Docket No. KLYCD-05007US1), U.S. Provisional Application No. 60/422,021, filed October 29, 2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD" (Attorney Docket No. KLYCD-05008US0), U.S. Patent Application No. 10/____, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD" (Attorney Docket No. KLYCD-05008US1), U.S. Provisional Application No. 60/422,011, filed October 29, 2002, entitled "TOOLS FOR IMPLANTING AN ARTIFICIAL VERTEBRAL DISK AND METHOD" (Attorney

Docket No. KLYCD-05009US0), and U.S. Patent Application No. 10/____,____, filed October 14, 2003, entitled "TOOLS FOR IMPLANTING AN ARTIFICIAL VERTEBRAL DISK AND METHOD" (Attorney Docket No. KLYCD-05009US1), which are all incorporated hereby by this reference.

FIELD OF THE INVENTION

[0003] This invention relates to an artificial vertebral disk replacement and method.

BACKGROUND OF THE INVENTION

[0004] The spinal column is a biomechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The biomechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and nerve roots.

[0005] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. Pain associated with such conditions can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals, and, in particular, for the elderly.

[0006] More particularly, over the years, a variety of intervertebral implants have been developed in an effort to relieve the pain associated with degenerative and dysfunctional disk conditions. For example, U.S. Patent 4,349,921 to Kuntz discloses an intervertebral disk prosthesis.

[0007] U.S. Patent 4,714,469 to Kenna discloses a spinal implant that fuses vertebrae to the implant. The implant has a rigid body that fits between the vertebra with a protuberance extending from a vertebral contacting surface and extends into the vertebral body.

[0008] U.S. Patent 5,258,031 to Salib et al. discloses another prosthetic disk with a ball that fits into a socket.

[0009] U.S. Patents 5,425,773 and 5,562,738 are related patents to Boyd et al. that disclose a disk arthroplasty device for replacement of the spinal disk. A ball-and-socket are provided to enable rotation.

[0010] U.S. Patent 5,534,029 to Shima discloses an articulated vertebral body spacer with a pair of upper and lower joint pieces inserted between the vertebra. An intermediate layer is provided to allow for movement between the upper joint piece and the lower joint piece.

[0011] U.S. Patent 5,782,832 to Larsen et al. discloses a two-piece ball-and-socket spinal implant with upper and lower plates for insertion within the intervertebral space.

[0012] U.S. Patent 6,156,067 to Bryan et al. discloses a prosthesis having two plates with a nucleus there between.

[0013] None of these solutions provide an implant that restores a wide range of natural movement.

[0014] Accordingly, there needs to be developed implants for alleviating such conditions, and for restoring natural movement.

SUMMARY OF THE INVENTION

[0015] An embodiment of the present invention is directed to providing an implant for alleviating discomfort associated with the spinal column. The implant is characterized by having a first plate and a second plate with a spacer therebetween. The spacer fits within cavities on each of the first and second plate.

[0016] Other aspects, objects, features and elements of embodiments of the invention are described or are evident from the accompanying specification, claims and figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1A is a side perspective view of an embodiment of the assembled implant of the invention. FIG. 1B is an alternative side perspective view of an embodiment of the assembled implant of the invention.

[0018] FIG. 2A and FIG. 2B show perspective views of the facing surfaces of the first plate and the second plate of an embodiment of the implant of the invention. FIG. 2C through FIG. 2F show cross-sectional views of the first plate and the second plate of an embodiment of the implant of the invention.

[0019] FIG. 3A is a perspective view of the spacer of an embodiment of the implant of the invention. FIG. 3B and FIG. 3C are cross-sections of the spacer of an embodiment of the implant of the invention taken at 90° angles respective to each other.

[0020] FIG. 4A is a cross-section of an embodiment of the implant of the invention taken along a plane parallel to the sagittal plane. FIG. 4B is a cross-section of an embodiment of the implant of the invention corresponding to a plane parallel to the location of the coronal plane after the implant has been implanted.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0021] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention

disclosed, the specification and drawings of all patents and patent applications cited in this application are incorporated herein by reference

[0022] FIG. 1A shows an embodiment of the implant **100** of the invention. The implant **100** has a first part **110** that is configured to mate with a first vertebra and a second part **120** that is configured to mate with a second vertebra. The first part **110** is a first or upper plate and the second part **120** is a second or lower plate. A third part **130** sits between the first part **110** and the second part **120**. The third part **130** acts as a spacer between the first part **110** and the second part **120** and facilitates pivotal movement of the first plate **110** and second plate **120**, relative to each other.

[0023] The upper plate **110** has a first surface **112** from which a keel **114** extends. The first surface **112**, or upper surface, abuts the vertebral body when the implant **100** is implanted. The first keel **114** extends into the vertebral body to anchor the implant into position. The keel **114** includes teeth **115** that assist in keeping the keel in position once the implant **100** is positioned between vertebral bodies. Generally, in a preferred embodiment that is to be implanted by an anterior approach, the teeth **115** point anteriorly in order to prevent the implant **100** from moving in an anterior direction. The second surface **116**, or lower surface, engages the third part **130** of the implant and faces the second plate **120**. The second surface **116** can form a planar surface that is parallel to the first surface **112**, or can form a planar surface that is unparallel to the first surface **112** in order, in one embodiment, to allow the first plate **110** and the second plate **120** to be able to pivot to a greater degree with respect to each other. It is to be understood that other factors such as the height of the spacer **130** can also be adjusted in order to increase the degree that the first plate **110** and the second plate **120** can pivot relative to each other.

[0024] When the implant is implanted between vertebral bodies the planar surfaces corresponding to the first surface **112** and the second surface **116** of the first plate **110** lie within, or substantially within, the axial

plane of the body while the first keel **114** (which is at or near a 90° angle from the surfaces **112, 116**) is aligned within the sagittal plane of the body.

[0025] The lower plate **120** has a first surface **122** from which a keel **124** extends. The first surface **122**, or lower surface, abuts the vertebral body when the implant **100** is implanted. The second keel **124** extends into the vertebral body to anchor the implant into position. The keel **124** includes teeth **125** that assist in keeping the keel in position once the implant **100** is positioned between vertebral bodies. Generally, in a preferred embodiment that is to be implanted by an anterior approach, the teeth **125** point anteriorly in order to prevent the implant **100** from moving in an anterior direction. The second surface **126**, or upper surface, engages the third part **130** of the implant and faces the first plate **110**. The second surface **126** can form a planar surface that is parallel to the first surface **122**, or can form a planar surface that is not parallel to the first surface in order, in one embodiment, to allow the first plate **110** and the second plate **120** to be able to pivot or rotate to a greater degree with respect to each other. The first surface **112** of the first plate **110** can form a planar surface that is parallel to a planar surface formed by the first surface **122** of the second plate **120** when the implant **100** is assembled and is in a neutral position (i.e., the position where the first plate **110** has not rotated relative to the second plate **120**). Alternatively, the first surface **112** of the first plate **110** can form a planar surface that is not parallel to the planar surface of the first surface **122** of the second plate **120** when the implant **100** is assembled and in a neutral position in order to accommodate the geometry of adjacent end plates of adjacent vertebral bodies. Such non-parallel surface in certain situations could eliminate a need to modify the surface of the end plates in order to accommodate the implant **100**.

[0026] As with the first plate, when the implant is implanted between vertebral bodies the planar surfaces corresponding to the first surface **122** and the second surface **126** of the second plate **120** lie within, or substantially within, the axial plane of the body while the second keel **124** (which is at or

near a 90° angle from the surfaces **122**, **126**) is aligned within the sagittal plane of the body.

[0027] FIG. **1B** shows an alternative perspective view of the implant **100** of the invention shown in FIG. **1A**. Again, the implant **100** has a first part **110** that is configured to mate with a first vertebra and a second part **120** that is configured to mate with a second vertebra. The third part **130** acts as a spacer to separate the first part **110** from the second part **120** and to allow the first plate **110** and the second plate **120** to pivot or rotate relative to each other.

[0028] FIG. **2A** shows a perspective view of the top plate **110** of the implant **100** of the invention. The first surface **112** of the top plate **110** is configured to contact the vertebral body when the implant **100** is implanted. The first surface **112** has a first keel **114** extending therefrom (shown in FIGS. **1A** and **1B**). The second surface **116** of the top plate **110** has a cavity **210** or socket formed thereon. The cavity is a convex cylindrical surface. An example of the relative dimensions of the cavity **210**, are discussed with respect to FIG. **2c** and FIG. **2d** below. The cavity **210** includes the shallow convex surface **211** with ends **213** and **215** that are, in this particular embodiment, substantially perpendicular to the surface **116**. These ends **213** and **215** essentially form perpendicular ends of a cylindrical void of cavity **210** defined by the convex surface **211** and the ends **213** and **215**. As will be described later with respect to the spacer **130**, the cavity **210** allows the spacer **130** to pivot or rotate about a first axis **217** that is about perpendicular to the ends **213** and **215** or in other words about an axis for the cylindrical void defined by cavity **210**. The ends **213** and **215** block motion of the spacer **130** about a second axis **219** that is perpendicular to the first axis **217**. In this embodiment, it is noted that the second axis **219** is parallel to the keels **114** and **124**. As can be seen in FIG. **2A**, the cavity **210** in this preferred embodiment includes side walls or ends **213** and **215** that have crests **233** and **235** respectively that project into the cavity **210**. Additionally, the convex

surface **211** has edges **234** and **236** with crests **237** and **239**. The crests **233**, **235**, **237**, and **239** allow a loose fit between the spacer **130** and the cavity **210**. This loose fit in turn allows the implant to twist in a direction that is perpendicular to the flat plain of the first plate **110** about an axis that is about parallel to the axis of the spine. Thus, the implant **100** allows the spine to have movement in three orthogonal degrees of freedom, namely (1) forward and backward bending movement, (2) lateral side-to-side bending, and (3) twisting movement. It is to be understood that the cavity **240** in the lower plate **120** can also have the same design as the cavity **210** in the upper plate **110** with an increase in the amount of twisting movement afforded by the implant **110**. As is noted elsewhere herein, loose fit generally between one or both of the cavities **210** and **240** and the spacer **130** can allow for twisting motion. Further the spacer **130** can also be made with crests on the curved surfaces and on the ends in order to afford similar twisting motion.

[0029] FIG. 2B shows a perspective view of the bottom plate **120** of the implant **100** of the invention. The first surface **122** of the bottom plate **120** is configured to contact the vertebral body when the implant **100** is implanted. As indicated above, the first surface **122** has a second keel **124** extending therefrom. The second surface **126** of the top plate **120** has a cavity **240** or socket formed thereon. The cavity **240** is a convex cylindrical surface. An example of the relative dimensions of the cavity **240** are discussed in more detail with respect to FIG. 2E and FIG. 2F below. The cavity **240** includes the shallow convex surface **241** with ends **243** and **245** that are in this particular embodiment substantially perpendicular to the surface **126**. These ends **243** and **245** essentially form perpendicular ends of a cylindrical void of cavity **241** defined by the convex surface **241** and the ends **243** and **245**. As will be described later with respect to the spacer **130**, the cavity **240** allows the spacer **130** to pivot or rotate about a first axis **247** that is about perpendicular to the ends **243** and **245** or, in other words, about an axis for the cylindrical void defined by cavity **240**. The ends **243** and **245** block motion of the spacer **130** about a second axis **249** that is perpendicular to the first axis **247**. In this

embodiment, it is noted that the first axis **247** is parallel to the keels **114** and **124**. It is also noted that in this embodiment the first axis **247** for second plate **120** about which the spacer **130** can pivot or rotate is perpendicular to the first axis **217** of the first plate **110** about which the spacer **130** can pivot or rotate. Thus, as will also be described below, the cavity of the first or upper plate **110** blocks movement of the spacer in a direction that is perpendicular to the keels **114** and **124** while allowing the first plate **110** to pivot or rotate about the first axis **217**, an axis that is perpendicular to the keels **114** and **124**. In this particular embodiment, generally, the spacer **130** is not required to move in order to emulate the degrees of freedom associated with the back as the ends of the cavities **210** and **240** block movement of the spacer **130**. However, it is to be understood that in a preferred embodiment, the fit of the spacer in the cavities **210** and **240** can be loose allowing the spacer to allow the first plate **210** to be able to twist somewhat relative to the second plate **240**. This twisting action would generally be about an axis that is perpendicular to the facing surfaces **116** and **126** of the first and second plates **110** and **120**, respectively. In other embodiments, the fit can be tighter in order to restrict such twisting action.

[0030] Turning now to **FIG. 2c** and **FIG. 2d**, a cross-section of the top plate **110** of the implant **100** of the invention is shown. **FIG. 2c** is a cross-section taken along a plane that would correspond to a plane that is parallel to the median sagittal plane of the body after the implant was implanted. The first surface **112** of the plate is configured to contact the vertebral body when the implant **100** is implanted. The first surface **112** has a first keel **114** extending therefrom that extends into the vertebral body when implanted. The second surface **116** of the upper plate **110** has a cavity **210** formed thereon. In this figure, the cavity **210** has a first dimension **212**. In the first dimension **212**, the cavity **210** is concave such that it is curved like the inner surface of a cylinder.

[0031] FIG. 2D is a cross-section taken along a plane that would correspond to a plane that is parallel to the frontal (coronal) plane of the body after the implant was implanted. FIG. 2D also illustrates the first surface 112 of the plate with the first keel 114. The second surface 116 of the upper plate 110 has a cavity 210 formed thereon. The cavity 210 has a second dimension 214. The second dimension 214 is in the form of a trough or "flattened-U" with a previously indicated concave bottom surface 211 and two ends or sidewalls 213, 215. As shown in FIG. 2C, the ends or sidewalls 213, 215 are parallel to each other and perpendicular to the bottom surface 211. However, as will be appreciated by those of skill in the art, the ends or sidewalls 213, 215 can be formed at an angle relative to each other without departing from the scope of the invention.

[0032] FIG. 2C and FIG. 2D are oriented to illustrate that the first dimension 212 shown in FIG. 2C and the second dimension 214 shown in FIG. 2D are perpendicular to each other.

[0033] Turning now to FIG. 2E and FIG. 2F, a cross-section of the lower plate 120 of an embodiment of the implant 100 of the invention is shown. FIG. 2E is a cross-section taken along a plane that would correspond to a plane that is parallel to the median sagittal plane of the body after the implant was implanted. FIG. 2E also illustrates the first surface 122 of the bottom plate 122 with the second keel 124. The cavity 240 has a first dimension 242. The first dimension 242 is in the form of a trough or "flattened-U" with a bottom concave surface 241 and two ends or sidewalls 243, 245. As shown in FIG. 2E, the ends or sidewalls 243, 245 are parallel to each other and perpendicular to the bottom surface 241. However, as will be appreciated by those of skill in the art, the ends or sidewalls 243, 245 can be formed at an angle relative to each other without departing from the scope of the invention.

[0034] FIG. 2F is a cross-section taken along a plane that would correspond to a plane that is parallel to the frontal (coronal) plane of the body after the implant was implanted. The first surface 122 of the plate is

configured to contact the vertebral body when the implant **100** is implanted. The first surface **122** has a first keel **124** extending therefrom. The second surface **126** of the bottom plate **120** has a cavity **240** formed thereon. In this figure, the cavity **240** has a second dimension **244**. In the second dimension **244**, the cavity **240** is concave such that it is curved like the inner surface of a cylinder.

[0035] FIG. 2c and FIG. 2d are oriented to illustrate that the first dimension **212** shown in FIG. 2c and the second dimension **214** shown in FIG. 2d are perpendicular to each other, while FIG. 2e and FIG. 2f illustrate that the first dimension **242** is perpendicular to second dimension **244**. Further, the curved first dimension **212** of FIG. 2c is oriented perpendicularly to the curved second dimension **244** of FIG. 2f, while the trough dimension **214** of FIG. 2d is oriented perpendicularly to the trough dimension **242** of FIG. 2e. It is noted that in FIGS. 2c through 2f that the facing surfaces **116** and **126** of the first and second plates are not parallel as shown in the other figures. In these figures the surfaces slope away from the first and second cavities **210** and **240**, respectively, in order to provide for a larger range of motion between the first and second plates.

[0036] In FIG. 3A, the spacer **130** is depicted in perspective view. The spacer **130** is dimensioned so that it has a curved or convex upper surface **310** and a curved or convex lower surface **320**, respectively, corresponding with the opposing concave surfaces in the upper plate **110** and the lower plate **120**.

[0037] As shown in FIG. 3A, the curved upper surface **310** is bordered along its curved edge by a pair of first sides **312**, **314** that are parallel to each other and along its flat edge by a pair of second sides **316**, **318** that are parallel to each other and perpendicular to the pair of first sides **312**, **314**. The orientation of the pair of first sides **312**, **314** to the pair of second sides **316**, **318** is such that the curved upper edges **322**, **324** of the first sides **312**, **314** extend toward the ends of the flat edges **321**, **323** of the pair of second sides

316, 318. The curved lower edges **326, 328** extend to meet the ends of the flat edges **325, 327** of the first sides **312, 314**.

[0038] FIG. 3B and FIG. 3C show cross-sections of the spacer **130**, shown in FIG. 3A. The cross-section of FIG. 3B is taken at a 90° angle from the cross-section shown in FIG. 3C. FIG. 3B is taken through a plane parallel to the ends **312, 314** and FIG. 3C is taken through a plane parallel to ends **316, 318**. The spacer **130** has a concave upper surface **310** and a concave lower surface **320** and pairs of parallel sides **312, 314** and **314, 318**.

[0039] FIG. 4A shows a cross-section of the implant **100** in its assembled condition taken along a plane that would correspond to a plane that is parallel to the median sagittal plane of the body after the implant was implanted. The implant **100** has a first upper plate **110** that is configured to mate with a first vertebra and a second lower plate **120** that is configured to mate with a second vertebra. The spacer **130** sits between the first plate **110** and the second plate **120**.

[0040] FIG. 4B shows a cross-section of the implant **100** in its assembled condition taken at 90° from the cross-section shown in FIG. 4A. Thus, the view of FIG. 4B is taken along a plane that would correspond to a plane that is parallel to the frontal (coronal) plane of the body after the implant was implanted.

[0041] It is to be understood that the embodiments of the invention can be made of titanium or medical grade stainless steel or other material that is approved for implantation in a patient and has appropriate characteristics. Alternatively, the spacer **130** can be made out of a polymer, and more specifically, the polymer is a thermoplastic with the other components made of the materials specified above. Still more specifically, the polymer is a polyketone known as polyetheretherketone (PEEK). Still more specifically, the material is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other

sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com). The spacer **130** can be formed by extrusion, injection, compression molding and/or machining techniques. This material has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. Further in this embodiment, the PEEK has the following additional approximate properties:

PROPERTY	VALUE
Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 GPa

[0042] It should be noted that the material selected may also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0043] The spacer can also be comprised of polyetherketoneketone (PEKK). Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and, generally, a

polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics.

[0044] Reference to appropriate polymers that can be used in the spacer can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0045] In operation, the implant **100** enables a forward bending movement and a rearward bending movement by sliding the upper plate **110** forward and backward over the spacer **130** relative to the lower plate **120**. This movement is shown as rotation about the axis **217** in **FIG. 4A**.

[0046] The implant **100** enables a right lateral bending movement and a left lateral bending movement by sliding the lower plate **120** side-to-side over the spacer **130** relative to upper plate **110**. This movement is shown as rotation about the axis **219** in **FIG. 4B**. Additionally, with a loose fit between the first plate, the second plate and the spacer, rotational or twisting motion along an axis that is along the spine and perpendicular to the first and second plates is accomplished.

[0047] To implant the implant **100** of this invention, the spine is exposed and then the intervertebral disk is removed. The implant is then inserted between two vertebrae and the wound is closed. This procedure can be followed for either an anterior approach or posterior approach. For an anterior approach, which due to the anatomy of the body may be preferred, the teeth would be pointed toward the anterior in order to aid in retaining the implant in place. For a posterior approach, the teeth would point posteriorly.

[0048] Additional steps, such as cutting channels into the vertebral bodies to accept the keels of the plates and assembling the implant by

inserting the spacer between the upper and lower plate prior to installation can also be performed without departing from the scope of the invention.

[0049] It is to be appreciated that although the first and second plates are depicted as having concave cavities and the spacer is depicted as having two convex surfaces that are oriented about perpendicular to each other, that other embodiments of the invention can have other configurations. For example, the first and second plates can have convex protrusions, such as, for example, cylindrical protrusions that are shaped to mate with concave surfaces of a spacer, with the concave surfaces of the spacer oriented about perpendicular to each other. In this embodiment, the convex protrusions of the first and the second plates could preferably each have a pair of parallel side walls that would act as the side walls in the depicted embodiments in order to block motion of the spacer. Also, it is to be appreciated that in still another embodiment, the spacer can have upper and lower truncated convex spherical surfaces with two pairs of side walls, instead of cylindrical surfaces with side walls, and be in the scope and spirit of the invention. In this embodiment, each of the first and second plates would have truncated concave spherical surfaces with a pair of side walls. In still a further embodiment, each of the first and second plates could have spherical protrusions with a pair of side walls and the spacer could have first and second spherical concave surfaces with two pairs of side walls joining the first and second spherical concave surfaces. Still alternatively, the first plate can have a concave surface and blocking side walls and the mating portion of the spacer can be convex with the second plate having a convex protrusion with the mating portion of the spacer, or being concave, with blocking side walls.

[0050] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in

order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and its equivalence.